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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/520,882

11/16/2005

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900145.403USPC

7056

500 7590 02/20/2009
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EXAMINER

KALLIS, RUSSELL

ART UNIT

PAPER NUMBER

1638

MAIL DATE

DELIVERY MODE

02/20/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/520,882	Applicant(s) BRUMBLEY ET AL.	
	Examiner RUSSELL KALLIS	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 9-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 9-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 November 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-7 and 9-18 are pending and examined. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Rejection of claims 16-18 under 35 U.S.C. 112, second paragraph, is withdrawn in view of Applicants' amendments.

Drawings

Figure 1 submitted 11/26/2008 does not indicate that it belongs to this case 10/520,882 or that it is a replacement drawing and does not constitute an acceptable replacement for Figure 1.

The submission of the replacement to Figure 16 is accepted.

Claim Rejections - 35 USC § 102

Claims 1-3, 5-7, and 9-13 remain rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 6,091,002 Asrar *et al.* issued July 18, 2000. This rejection is maintained for the reasons of record set forth in the Official action mailed 5/29/2008. Applicant's arguments filed 11/26/2008 have been considered but are not deemed persuasive.

Applicant asserts that the Asrar patent does not anticipate because it does not teach the instantly claimed sequences with sufficient specificity and that the Asrar patent, wherein Applicant only points to claims 1-4, merely teaches generic enzymatic activities encoded by unidentified genes (response page 7). This is not persuasive because the reference when viewed as a whole clearly provides support (i.e. teaches) for the biological production of PHA using the PHA pathway genes from *A. eutropha*, that are the instantly claimed SEQ ID NO: 1, 4 and 7. Further, Applicants' remark that the activities are speculative is not well founded because those

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activities of the PHA biosynthetic pathway were well known and their genes sequenced and publically available well before the earliest priority claim of the instant filing (see 002' Patent in column 2 lines 57-67), and thus in response to Applicants' the 002' does not provide sufficient specificity" and does not disclose the specific combination to meet the requirement for anticipation under 35 USC 102(b), the specification of the 002' Patent does provide support that it anticipates the instantly claimed invention (see claim 12 for sugarcane).

Applicant asserts that SEQ ID NO: 11 of the 002' Patent (Asrar) does not have any significant identity to the instantly claimed *PhaA* gene of SEQ ID NO: 1 (response page 8). This is not persuasive because the 002' Patent teaches that SEQ ID NO: 11 is the gene product of the *bktB* gene a thiolase closely related to *PhbA* from *A. eutropha*. However, the 002' Patent does teach the *PhaA* or *PhbA* gene from *A. eutropha* (see remarks supra).

Applicant asserts that the 002' Patent does not disclose the specific combination of SEQ ID NO: 1, SEQ ID NO: 4, and SEQ ID NO: 7 (response page 8). Applicant is invited to inspect the 002' Patent from column 99 line 10 to column 100 line 40. Where the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Whether the rejection is based on "inherency" under 35 USC 102, on "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. See *In re Best, Bolton, and Shaw*, 195 USPQ 430 (CCPA 1977).

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Claims 1-7 and 9-18 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,091,002 Asrar *et al.* issued July 18, 2000 in view of U.S. Patent 6,475,734 filed September 28, 2000. This rejection is maintained for the reasons of record set forth in the Official action mailed 5/29/2008. Applicant's arguments filed 11/26/2008 have been considered but are not deemed persuasive.

Applicant asserts that the 002' Patent fails to teach the *phaABC* genes from *R. eutropha* i.e. *A. Eutropha*. See arguments *supra*.

Applicant asserts that the Examiner has not established by technical reasoning that one of ordinary skill would have a reasonable expectation of success

Applicant asserts that successful transformation of sugarcane with multiple genes was not known (response page 11). Clearly, Applicant has missed the obvious because the 002' Patent is drawn to sugarcane transformed with multiple genes of the PHA pathway(see claim 12 of the 002' Patent and arguments *supra*).

Applicants' remarks about gene silencing are not well founded. Applicant asserts that transforming plants with multiple genes will result in gene silencing (response page 11) is not persuasive because gene silencing is known to occur when the multiple transgenes are identical to each other or endogenous plant genes. In this case the genes are from different steps in the PHA biosynthetic pathway from a bacteria known to synthesize PHA, and since it is a plant being transformed with a bacterial pathway there is no basis in fact or the prior art for any of Applicants' assertions with respect to gene silencing.

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Applicant asserts that the Examiner has not provided technical reasoning in establishing obviousness and the burden of proof is upon the examiner to provide such (response page 11).

The previous section from the previous office action is repeated for Applicants.

It would have been obvious to further engineer the sugarcane of Asrar to incorporate the sequences taught by the '734 Patent. One of ordinary skill would have been motivated by the teachings of Asrar that production of polyhydroxybutyrate in plants was an efficient way to produce bioplastic and by the teachings of the '734 Patent that connections to fatty acid biosynthesis could be engineered to redirect metabolites to polyhydroxyalkanoate production in crop plant species and that one would have a reasonable expectation of success of transforming plants and manipulating the biochemical pathways of plants because the techniques for transforming plants such as sugarcane were known and the polynucleotide sequence that would hybridize to SEQ ID NO: 31, 28 or 19 were known in that art and their activities identified for their usefulness in genetic engineering plants to produce biopolymer in plants.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to RUSSELL KALLIS whose telephone number is (571)272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Russell Kallis/
Primary Examiner, Art Unit 1638
February 6, 2009